

## REMARKS

Applicants thank the Examiner for an informal telephonic interview held September 7, 2005, in which she indicated potentially allowable subject matter. The Office Action mailed September 27, 2005 indicates that an Interview Summary was attached to the Office Action, but applicants did not receive one; applicants request a copy of this Interview Summary to complete the record. Applicants also acknowledge the conclusion at page 4 of the Office Action that claims 27-31 (which recite specific SEQ ID numbers) are allowable over the prior art of record. Claim 1 has been amended to be of the same scope as claim 27, and other claims have been amended accordingly. Entry of the present Reply/Amendment is respectfully requested, since it would reduce the issues raised in the final Office Action of September 27, 2005, and is in response suggestions by the Examiner in the informal telephonic interview and to the statement by the Examiner in the Office Action that the amended claims would be free of the prior art.

A Reply/Amendment to the Office Action mailed September 27, 2005 was filed on December 22, 2005. In an Advisory Action mailed January 19, 2006, the Examiner noted a few minor errors in the amendments, which she alleged added new matter; and she thus declined to enter the Reply. The present Supplemental Reply is revised to correct those errors in the amended claims. (1) Claim 12 is amended to recite a "host cell" into which has been introduced a heterologous nucleic acid encoding the recited polypeptides. Claims 13 and 14, which depend from claim 12, therefore have correct antecedent base. It is noted that the recitation of "a host cell" etc. in claim 12 was, in fact, present in the Reply filed June 16, 2005 and was inadvertently omitted from the Reply filed December 22, 2005. Therefore, in restoring that recitation in the present Supplemental Reply, the claim language is fully supported in the specification, no new matter has been added, and the scope of the claims has not been narrowed. (2) The mis-spelling "CABP" has been corrected to "C4BP." Support for the correct spelling is found, for example, in claim 1 and on page 1, line 16 of the specification. The Supplemental Reply is otherwise identical to the Reply filed on December 22, 2005.

Claims 1, 4, 12 and 29-31 have been amended to address concerns raised by the Examiner. The amendments do not add new matter and are fully supported by the

specification. In addition to the claims which were previously canceled, claims 2 and 27 have been canceled, as being duplicative of amended claim 1; claim 25 as being duplicative of claim 23; and claim 28 as being duplicative of amended claim 4. These claims are canceled without prejudice or disclaimer. Claims 1, 3-17, 20, 22-24, 26 and 29-31 are currently under consideration.

Restriction and election of species

With regard to the species election, applicants request that if no prior art is found against the elected species, additional species be examined and, if no art is found against them, the generic claim, and dependent claims directed to specific species, be allowed. Furthermore, it is noted that claim 1 recites a generic recombinant multimeric protein, comprising two polypeptide fusion monomers, A and B, each of which comprises a C-terminal fragment of either the  $\alpha$  or  $\beta$  chain of C4BP and "a polypeptide fragment which is heterologous to the [ $\alpha$  or  $\beta$  chain, respectively]." Applicants urge that if a recombinant multimeric protein comprising the recited fragments of the  $\alpha$  and  $\beta$  chains of C4BP is free of the prior art of record, such a recombinant multimeric protein would be free of the prior art, regardless of which heterologous polypeptide fragments are present in the multimer; therefore, additional searches should not be required.

With regard to claim 20, applicants request that, once claim 1, from which it depends, is found allowable, claim 20 be rejoined, per *In re Ochiai*, 37 USPQ2d 1127 (Fed. Cir. 1995).

Rejections under 35 U.S.C. §112, second paragraph

Applicants disagree that the term "contained in SEQ ID NO:\_\_\_\_" is indefinite. Nevertheless, at the suggestion of the Examiner in an informal interview held September 7, 2005, claims which recite a particular SEQ ID number have been amended to recite "contained within the amino acid sequence represented by SEQ ID NO:\_\_\_\_." The fragment can be any fragment within the amino acid sequence of the recited SEQ ID number, provided that the fragment fulfills the requirement of the claim that it contains one or two cysteine residues which can participate in a disulfide bridge between the two chains. The amendment does not narrow the scope of the claims.

The Examiner appears to be concerned with an apparent discrepancy between claims that recite "a ligand of the immune system" (e.g. claims 28-31) and "a specific ligand of the immune system" (e.g. claim 4). Applicants disagree that the recitation of the term "specific" is indefinite in this context. Nevertheless, in an effort to expedite prosecution, the term "specific" has been deleted from claim 4. A skilled worker would know, in light of the specification, what is meant by the term "ligand of the invention." Typical examples of suitable ligands of the immune system are provided in the specification, e.g. at page 6, first full paragraph. The amendment does not narrow the scope of the claim.

Deposit requirement

Documentation that a deposit was made in accordance with the terms of the Budapest Treaty was included with the Amendment filed September 27, 1999. Another copy of the documentation is enclosed for the convenience of the Examiner.

Rejections under 35 U.S.C. § 102(b)

Applicants disagree with the allegation that claim 1 and others, as presented in the Reply of June 16, 2005, are anticipated by WO91/11461, for reasons of record. Nevertheless, in an effort to expedite prosecution, the present claims have been amended to recite that the C-terminal fragments of the  $\alpha$  and  $\beta$  chains of C4BP (which are present in polypeptide fusion monomers A and B) are contained within amino acid sequences represented by SEQ ID NO:7 and SEQ ID NO:8, respectively. The reference does not suggest or disclose the particular, selected sequences which are recited in the claims. To anticipate a claim, a reference must disclose all material elements of the claim, which is clearly not the case here. The Examiner has indicated in the "Conclusion" of the Office Action that claims of the present scope are free of the prior art of record. Therefore, it is requested that the rejection under 35 U.S.C. § 102(b) be withdrawn.

In view of the preceding arguments and amendments, it is believed that the application is in condition for allowance, which action is respectfully requested.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 22-0261, under Order No. 31640-134353.

Respectfully submitted,

Date: January 27, 2006

  
\_\_\_\_\_  
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Fax émis par:  
Fax reçu de 202 962 8300  
09/22/99 17:14 FAX 202 962 8300

GUTMANN-PLASSERAUD le 24/09/99 16:28 A4 NORM Pg: 2/11 004

VENABLE

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Examiner: Basi, N.  
Art Unit: 1646

In Re PATENT APPLICATION of

Applicant(s) : David KLATZMANN, et al.

Application No.: 08/983,474

Filed : June 30, 1998

For :  $\alpha$ - $\beta$  C4BP-TYPE  
RECOMBANANT  
HETEROMULTIMERIC  
PROTEINS

Attorney Dkt.: 31640-134353(formerly GUPLA-0007)

)  
) DECLARATION OF  
) DEPOSIT OF  
) BIOLOGICAL  
) MATERIAL  
) UNDER THE TERMS  
) OF THE  
) BUDAPEST TREATY  
)  
)  
)

September 27, 1999

Honorable Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Sir:

I, the undersigned, declare that:

1.

I am P<sup>r</sup> JHM Cohen and an authorized signatory for the  
UNIVERSITE PIERRE ET MARIE CURIE (PARIS VI) located at Etablissement  
Public, 4, place Jussieu, F-75252 Paris Cedex 05, France and/or for the  
UNIVERSITE DE REIMS CHAMPAGNE-ARDENNES, located at Etablissement  
Public, Villa Douce, 9, boulevard de la Paix, F-51097 Reims, France, joint owners

(08/983,474)

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Fax émis par:  
09/12/98 17:14 PAX 202 862 8300GUTMANN-PLASSERAUD .. le 24/05/98 16:28 M4 NORM Pg: 3/11  
VENABLE 005

of the above identified patent application, the assignment being recorded on Reel 9374, Frame 0405.

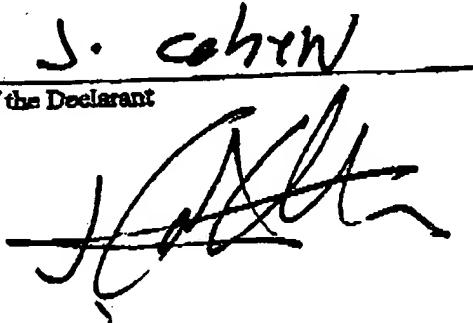
2. Two plasmids were deposited under the terms of the Budapest Treaty on July 12, 1995, with the Collection National de Culture de Micro-organismes at the Pasteur Institute, located in Paris, France, under Accession Numbers: I-1610 and I-1611.
3. The above named depository is an International Depository Authority as established under the Budapest Treaty, and I affirm that all restrictions on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.
4. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date

25/12/98

By:

Name of the Declarant

J. Cohen


# CNCM

Collection Nationale  
de Cultures de Microorganismes  
**INSTITUT PASTEUR**  
25, Rue du Docteur Roux  
75724 PARIS CEDEX 15

Tel : (33-1) 45 68 82 50  
Fax : (33-1) 45 68 82 36

Paris, le 26 septembre 1995

à CENTRE HOSPITALIER UNIVERSITAIRE DE REIMS  
Hôpital ROBERT DEBRÉ  
51092 REIMS CEDEX

A l'attention de Monsieur J.H.M. COHEN,  
Laboratoire d'Immunologie

Obj : ACCORDS DE CONFORMITE  
N/r : CNCM - YG - 4822.509  
Copie : Monsieur C. SEVIRIN, Président  
Université Reims Champagne-Ardenne, Service Recherche - 9, Boulevard de la Paix  
51100 REIMS

Les microorganismes désignés ci-après ont été déposés auprès de la CNCM aux termes du Traité de Bucarest au nom de :

Professeur JHM COHEN - PU - PH  
Université Reims Champagne-Ardenne  
Service Recherche  
"Villa Douce"  
9, boulevard de la Paix  
51100 REIMS

par vos soins en tant que responsable scientifique à la date du 12 JUILLET 1995

Références d'identification

Multi CD16 C4b<sub>1</sub>p alpha  
Multi CD4 C4b<sub>1</sub>p bêta

Numéros d'ordre attribués par la CNCM

I - 1610  
I - 1611

Pour chacun des microorganismes désignés ci-dessus vous trouverez ci-joint deux échantillons d'une subculture à partir du lot '001' ou du lot 'Ec2', conservés en azote liquide, afin de vérifier le maintien de leurs propriétés originales.

Nous vous prions de bien vouloir nous renvoyer, après examen, les formules ci-jointes, dûment remplies et signées.

Les lots '001' ou 'Ec2', préparés par la CNCM, sont destinés à répondre pendant 35 ans aux requêtes en remise d'échantillons conformément à la réglementation applicable.

En cas de non-réponse à une demande de contrôle de conformité dans le délai de trois mois après réception des échantillons, les propriétés de la subculture en question sont considérées identiques aux propriétés de la subculture ayant fait l'objet du dépôt initial.

  
Mme Y. CERISIER  
DIRECTEUR ADMINISTRATIF DE LA CNCM

# CNCM

Collection Nationale  
de Cultures de Microorganismes

## INSTITUT PASTEUR

28, Rue du Docteur Roux  
75724 PARIS CEDEX 15

Tel : (33-1) 45 68 82 60  
Fax : (33-1) 46 68 82 36

## CONTROLE DE CONFORMITE AUTHENTICITY CHECK

Deux échantillons d'une subculture à partir du lot "001", conservé en azote liquide, du microorganisme désigné ci-après  
Two samples of a preparation out of a batch "001", stored in liquid nitrogen, of the microorganism identified hereunder

Multi CD16 C4bp alpha

I - 1610

REFERENCE D'IDENTIFICATION  
IDENTIFICATION REFERENCE

NUMERO D'ORDRE CNCM  
CNCM accession number

déposé auprès de la CNCM aux termes du Traité de Budapest le 12 JUILLET 1995 par  
deposited with the CNCM under the Budapest Treaty on JULY, 12, 1995 by

Professeur J.H.M COHEN - I.U. • PH  
Université Reims Champagne-Ardenne  
Service Recherche  
"Villa Douce"  
9, boulevard de la paix  
51100 REIMS

a fait l'objet à la date du 26.09.1995 de la part de la CNCM d'une demande de contrôle de conformité auprès du scientifique désigné ci-après, responsable du matériel biologique transmis à la CNCM le 12.07.1995 en tant que dépôt initial.  
was subjected by CNCM on 09.26.1995 to a request for an authenticity check by the hereunder designated scientist responsible for the microbial material transmitted to CNCM on 07.12.1995 in the case of the original deposit.

Monsieur J.H.M. COHEN  
Laboratoire d'Immunologie  
CENTRE HOSPITALIER UNIVERSITAIRE DE REIMS  
Hôpital Robert Debré  
51092 REIMS CEDEX

COCHER LE CASE QUI CONCOURT  
MARK WITH A CHECK THE APPLICABLE BOX



Le soussigné atteste que la subculture soumise pour examen porte toutes les propriétés connues du microorganisme identifié ci-dessus, qu'elle répond aux revendications des demandes de brevet y relatives, et qu'un échantillon du même lot peut être remis à une partie autorisée ou certifiée.  
The undersigned testifies the preparation here examined bears all known properties of the above identified microorganism, it corresponds to the claims in the relevant patent applications, and a sample of the same batch can be released to an authorized or certified party.



Autres conclusions:  
Other findings:

DATE.  
DATE

SIGNATURE  
SIGNATURE



19 X 95

NOM ET ADRESSE DU SCIENTIFIQUE (SI DIFFERENTS DES INDICATIONS CI-DESSUS)  
NAME AND ADDRESS OF THE SCIENTIST (AS FAR AS DIFFERENT FROM THE INDICATION GIVEN ABOVE)

**CNCM**Collection Nationale  
de Cultures de Microorganismes**INSTITUT PASTEUR**25, Rue du Docteur Roux  
75724 PARIS CEDEX 15Tel : (33-1) 45 68 82 50  
Fax : (33-1) 45 68 82 36**CONTROLE DE CONFORMITE**  
**AUTHENTICITY CHECK**

Deux échantillons d'une subculture à partir du lot "Ec2", conservé en azote liquide, du microorganisme désigné ci-après  
*Two samples of a preparation out of a batch "Ec2", stored in liquid nitrogen, of the microorganism identified hereunder*

**Multi CD4 C4bp bêta****I - 1611**REFERENCE D'IDENTIFICATION  
 IDENTIFICATION REFERENCENUMERO D'ORDRE CACHÉ  
 CACHÉ ACCESSOIRE NUMERO

déposé auprès de la CNCM aux termes du Traité de Budapest le 12 JUILLET 1995 par  
 deposited with the CNCM under the Budapest Treaty on JULY, 12, 1995 by

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 Université Reims Champagne-Ardenne  
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 was subjected by CNCM on 09.26.1995 to a request for an authenticity check by the hereunder designated scientist responsible for the microbial material transmitted to CNCM on 07.12.1995 in the case of the original deposit.

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 CENTRE HOSPITALIER UNIVERSITAIRE DE REIMS  
 Hôpital Robert Debré  
 51092 REIMS CEDEX

COCHER LA CASE QUI CONCOURS  
 MARK WITH A CROSS THE APPLICABLE BOX

Le susmentionné atteste que la subculture soumise pour examen porte toutes les propriétés connues du microorganisme identifié ci-dessus, qu'elle répond aux revendications des demandes de brevet y relatives, et qu'un échantillon du même lot peut être remis à une partie autorisée ou certifiée.  
 The undersigned testifies the preparation here examined bears all known properties of the above identified microorganism, it corresponds to the claims in the relevant patent applications, and a sample of the same batch can be released to an authorized or certified party.



Autres conclusions:  
 Other findings:

DATE.  
 DATESIGNATURE  
 SIGNATURE

14 X 45

NOM ET ADRESSE DU SCIENTIFIQUE (SI DIFFÉRENTS DES INDICATIONS CI-DESSUS)  
 NAME AND ADDRESS OF THE SCIENTIST (AS FAR AS DIFFERENT FROM THE INDICATIONS ABOVE)

BEST AVAILABLE COPY